

## DETAILED ACTION

### *Status of the Application*

This Office Action is in response to applicant's remarks filed on 4/1/2008.

Claim(s) 1-32 are pending. Claim(s) 28-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claim(s) 3, 9-26 are withdrawn from further consideration as being drawn to a non-elected species. Applicant's election **without traverse** of the restriction requirement in the reply is acknowledged. The requirement is deemed proper and is therefore made FINAL. Claim(s) 1-2, 4-8, 27 are examined herein insofar as they read on the elected invention and species.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 1-2, 5-8 are rejected under 35 U.S.C. 103(a) as being obvious over Weidner (US Patent 6,217,877 B1) in view of Sorm ("Sesquiterpenes with Ten-Membered Carbon Rings. A Review", J. Agr. Food Chem., 19: 1081-1087, 1971, of record).

The instant claims are directed to a method of treating a subject with a hepatitis C virus infection by administering a composition comprising a sesquiterpene lactone of the formula in claim 5.

Weidner teach that the plant *Parthenium integrifolium* and more specifically to pharmaceutical compositions derived from it as well as the use of its parts, extract, or components thereof for the preparation of medicines for the alleviation of pain or for the treatment or prevention of inflammatory or autoimmune disorders (col. 1, lines 16-22). A number of chemicals have been identified as major components of *Parthenium integrifolium* extracts, in which one group is sesquiterpene lactones (col. 1, lines 35-37). The therapeutic action of the administration of *Parthenium integrifolium* or parts, extract, or components thereof, is relevant to all known autoimmune diseases, for example hepatitis (col. 4, lines 5-19).

However, Weidner fails to specifically disclose a sesquiterpene lactone of the formula in claim 5.

Sorm merely teaches that parthenolide is a well known sesquiterpene lactone (pg. 1083, top left column).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to have substituted the specific sesquiterpene lactone, parthenolide, as taught by Sorm with the sesquiterpene lactone in the method of treating hepatitis C infection as taught by Weidner.

A person of ordinary skill in the art would have been motivated to have substituted the specific sesquiterpene lactone, parthenolide, as taught by Sorm with the sesquiterpene lactone in the method of treating hepatitis C infection as taught by Weidner because: (1) both Sorm and Weidner as analogous art as they both disclose sesquiterpene lactones; (2) Weidner teach broadly that sesquiterpene lactones are a major component of *Parthenium integrifolium* extracts, which may be used to treat hepatitis; (3) Sorm teaches that parthenolide is a well known sesquiterpene lactone; and (4) because of the functional equivalency between parthenolide and another sesquiterpene lactone. Therefore, the skilled artisan would have had a reasonable expectation of success in treating a subject with a hepatitis C infection by administering a composition comprising parthenolide.

Claim(s) 4 and 27 are rejected under 35 U.S.C. 103(a) as being obvious over Weidner (US Patent 6,217,877 B1) in view of Sorm ("Sesquiterpenes with Ten-Membered Carbon Rings. A Review", J. Agr. Food Chem., 19: 1081-1087, 1971, or record) as applied to claims 1-2, 5-8 and further in view of Tan et al. ("Hepatitis C Therapeutics: Current Status and Emerging Strategies", Nature Reviews 1:867-881, 2002, of record).

The instant claims are directed to a method of treating a subject with a hepatitis C virus infection by administering a composition comprising a sesquiterpene lactone of the formula in claim 5 and a second therapeutic agent.

Weidner and Sorm teach as discussed above, however, do not specifically teach a second therapeutic agent.

Tan et al. teach that IFN $\alpha$ -based therapies, such as Intron A, are well-known therapies for the treatment of hepatitis C virus infection (Table 1).

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to have combined Intron A as taught by Tan et al. with the composition comprising parthenolide, as taught by Sorm in the method of treating hepatitis C infection as taught by Weidner.

A person of ordinary skill in the art would have been motivated to have combined Intron A as taught by Tan et al. with the composition comprising parthenolide, as taught by Sorm in the method of treating hepatitis C infection as taught by Weidner because of the therapeutically additive effect of using two active agents for the same purpose of treating hepatitis C infection. Therefore, the skilled artisan would have had a reasonable expectation of success in treating a subject with a hepatitis C infection by administering a composition comprising parthenolide and Intron A.

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... The idea of combining them flows logically from their

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having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong S Chong/  
Examiner, Art Unit 1617

YSC